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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/722,142 | 11/24/2003 | Dan T. Simionescu | CXU-379 | 4675 |
| 22827 | 7590 | 04/06/2006 | EXAMINER | |
| DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449 | | | KUMAR, PREETI | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1751 | |
| DATE MAILED: 04/06/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/722,142 | | SIMIONESCU ET AL. | |
| | Examiner | | Art Unit | |
| | Preeti Kumar | | 1751 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/21, 12/17, 1/10</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Non-Final Rejection

Response to Amendment

1. Applicant's election with traverse of Group III claims 20-29 in the reply filed on 1/17/2006 is acknowledged. The traversal is on the ground(s) that Group III, claims 20-29 and Group IV, claims 30-40 are related as combination/subcombination and accordingly should be pose a burden on the examiner. This is not found persuasive because the fixed tissue of claims 20-29 has separate utility by itself or in other combinations (MPEP § 806.05)) such as in the production of thin layer sections for transmission electron microscopy.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 20-29 are pending. Claim 20 is independent.
3. Claims 1-19 and 41-46 are cancelled. Claims 30-40 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 22, 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the limitation "...following exposure to elastase..." in claim 20.

There is insufficient antecedent basis for this limitation in the claim.

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Regarding claims 22, 25-27, the court has held that compositions are indefinite for being defined in terms of properties alone. *Ex parte Spacht*, 165 USPQ 409 (PO BdPatApp 1969); *Ex parte Slob,* 157 USPQ 172 (PO BdPatApp 1967); *Ex parte Pulvari*, 157 USPQ (PO BdPatApp 1966);

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 20, 21, 23-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bachhuber et al. (US 4,588,579).

Bachhuber et al. teach a process for the production of thin sections of biological tissue of any desired origin can be cut up into samples with a thickness of 2-100 nm, without destruction of the tissue and cell structures, when the free water contained in the tissue is replaced by a non-volatile, readily sectile resin. See col.1,ln.5-25.

In example Bachhuber et al. illustrate that pieces of liver, hypophysis (pituitary), retina and diaphragm muscle of the rat were fixed in an aqueous solution which contained 1% by weight glutaraldehyde and 1% by weight tannic acid. See col.5, ln.17-20. Accordingly the teachings of Bachhuber et al. anticipate the material limitations of the instant claims.

However, Bachhuber et al. are silent as to the fixed tissue comprising crosslinked elastin and crosslinked collagen. However, it is reasonable to presume that said limitations are encompassed by the invention of Bachhuber et al. because the presumption is supported by the use of similar materials (i.e. muscle tissue) and in the similar production steps (i.e. contacted with phenolic tannin cross linking agent and glutaraldehyde cross linking agent) to produce a fixed tissue. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

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10. Claims 22, 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachhuber et al. (US 4,588,579).

Bachhuber et al. are relied upon as set forth above. However Bachhuber et al. do not teach the claimed properties of the fixed tissue having 60 % less calcification, a thermal denaturation temperature greater than 70 C, less than 20% degradation after 48 hours and also do not teach fixing porcine, bovine or heart tissues.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, arrive at a fixed tissue having the properties recited by the instant claims, with a reasonable expectation of success because Bachhuber et al. teach that tissue of any desired origin can be fixed with phenolic tannin and glutaraldehyde crosslinking agents and furthermore it is reasonable to presume said properties to calcification, denaturation and degradation are encompassed by the fixed tissue of Bachhuber et al. because the presumption is supported by the use of similar materials (i.e. biological tissue) and in the similar production steps (i.e. contacted with phenolic tannin and glutaraldehyde) to produce the fixed tissue. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

11. Claims 20-21, 23-24, and 28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adkisson (US 6,645,764).

Adkisson teach neocartilage matrix of skeletal muscle and other connective tissue is fixed with glutaraldehyde and tannic acid. See col.6,ln.1-10 and col.14,ln.11-

12. Adkisson teach that the neocartilage may be mammalian neocartilage, including

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human and porcine, or avian neocartilage. See col.10,ln.42-50. Accordingly the teachings of Adkisson anticipate the material limitations of the instant claims.

However, Adkisson is silent as to the fixed tissue comprising crosslinked elastin and crosslinked collagen. However, it is reasonable to presume that said limitations are encompassed by the invention of Adkisson because the presumption is supported by the use of similar materials (i.e. neocartilage, skeletal muscle and other connective tissue) and in the similar production steps (i.e. contacted with phenolic tannin cross linking agent and gluteraldehyde cross linking agent) to produce a fixed tissue. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

12. Claims 22, 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adkisson (US 6,645,764).

Adkisson is relied upon as set forth above.

Adkisson are silent as to the claimed properties of the fixed tissue having 60 % less calcification, a thermal denaturation temperature greater than 70 C, less than 20% degradation after 48 hours.

However, it is reasonable to presume said properties to calcification, denaturation and degradation are encompassed by the fixed tissue of Adkisson because the presumption is supported by the use of similar materials (i.e. biological tissue) and in the similar production steps (i.e. contacted with phenolic tannin and gluteraldehyde) to produce the fixed tissue. The burden is upon the applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

14. Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Preeti Kumar whose telephone number is 571-272-1320. The examiner can normally be reached on M-F 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Mc Ginty can be reached on 571-272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DOUGLAS MCGINTY
SUPERVISORY PATENT EXAMINER

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Examiner
Art Unit 1751

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